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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,186	09/25/2003	Craig A. Rosen	PS952	5695

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HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
SHAW, AMANDA MARIE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,186	ROSEN ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 15-16, and 22, drawn to nucleic acid molecules and compositions containing same, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1, 243, 320.1, and 325, and Class 514, subclass 44.

II. Claims 11-13, and 16, drawn to polypeptides, classified in Class 530, subclass 350 and 514.

III. Claim 14, drawn to an antibody, classified in Class 530, subclass 387.1.

IV. Claim 18 , drawn to a method of preventing, treating, or ameliorating a immune disorder by administering a polypeptide, classified in class 514, subclass 2.

V. Claim 19 , drawn to a method of diagnosing a immune disorder based on the presence or absence of a mutation, classified in class 435, subclass 6.

VI. Claim 20 , drawn to a method for diagnosing a immune disorder using polypeptide expression detection, classified in class 435, subclass 7.1.

VII. Claims 21 and 24, drawn to a method for identifying a binding partner to a polypeptide and said binding partner composition, classified in class classified in Class 436, subclass 501.

VIII. Claim 23, drawn to a method of identifying an activity of a protein in a cell, classified in class 435, subclass 7.1 and 69.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and physicochemical properties. Invention I is drawn to nucleic acids whereas Invention II is drawn to

polypeptides. Nucleic acids are composed of nucleotides and polypeptides are composed of amino acids. Accordingly, these compounds are independent and distinct from one another due to their diverse chemical structure, their expected different chemical properties, modes of action, different effects and reactive conditions. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention II do not requires the particular products of the nucleic acids of Invention I since the proteins of Invention II can be isolated from natural sources or chemically synthesized.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of being used together. Furthermore, the nucleic acids of Invention I, which are composed of nucleotides, are chemically and biologically distinct from the antibodies of Invention III, which are composed of amino acids and have distinct structural and immunological properties.

Inventions I and IV, I and VI, I and VII, and I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Invention I are not disclosed as capable of use in the method of preventing, treating or ameliorating

a immune disorder in Invention IV, the method of diagnosing a immune disorder in Invention VI, the method for identifying a binding partner to a polypeptide in Invention VII, or the method for identifying an activity of a protein in a cell in Invention VIII.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Invention I are nucleic acid molecules and compositions containing nucleic acid molecules. The product as claimed by Invention I can be used in a materially different process such as synthesizing primers and probes or used in antisense therapy.

Inventions II and III are patentably distinct in structural and functional properties. Invention II is drawn to polypeptides, while Invention III is drawn to antibodies. Although both proteins and antibodies are composed of amino acids, the antibodies of Invention III have distinct structural limitations not required of the polypeptides of Invention II. Furthermore, antibodies have particular immunological functions that distinguish them from other polypeptides.

Inventions II and IV, II and VI, II and VII, and II and VIII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In

the instant case the polypeptides of Group II can be used in a material different process such as assays for protein purification.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention II are not required in the method of method of diagnosing an immune disorder based on the presence or absence of a mutation in Invention V.

Inventions III and IV, III and V, III and VI, III and VII, and III and VIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Invention III are not disclosed as capable of use in the method of Inventions IV, V, VI, VII, or VIII. The method of Invention IV requires the use of a polypeptide to prevent treat or ameliorate an immune disorder. The method of Invention V requires the presence or absence of a mutation to diagnose an immune disorder. The method of Invention VI requires the determination of expression of a polypeptide to diagnose an immune disorder. The method of Invention VII requires a polypeptide and its binding partner to identify a binding partner to the polypeptide. The method of Invention VIII requires a protein to identify an activity in a biological assay.

Inventions IV and V, IV and VI, IV and VII, and IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention IV requires the use of a polypeptide to prevent treat or ameliorate an immune disorder. The method of Invention V requires the presence or absence of a mutation to diagnose an immune disorder. The method of Invention VI requires the determination of expression of a polypeptide to diagnose an immune disorder. The method of Invention VII requires a polypeptide and its binding partner to identify a binding partner to the polypeptide. The method of Invention VIII requires a protein to identify an activity in a biological assay.

Inventions V and VI, V and VII, and V and VIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention V requires the presence or absence of a mutation to diagnose an immune disorder. The method of Invention VI requires the determination of expression of a polypeptide to diagnose an immune disorder. The method of Invention VII requires a polypeptide and its binding partner to identify a binding partner to the polypeptide. The method of Invention VIII requires a protein to identify an activity in a biological assay.

Inventions VI and VII, and VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention VI requires the determination of expression of a polypeptide to diagnose an immune disorder. The method of Invention VII requires a polypeptide and its binding partner to identify a binding partner to the polypeptide. The method of Invention VIII requires a protein to identify an activity in a biological assay.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different method, which have different process steps and different objectives. The method of Invention VII requires a polypeptide and its binding partner to identify a binding partner to the polypeptide. The method of Invention VIII requires a protein to identify an activity in a biological assay.

Sequence Election Requirement Applicable to All Inventions

3. In addition, each Invention detailed above reads on a patentably distinct nucleic acid or amino acid sequence. Each nucleotide sequence has a different melting temperature, a different specificity of hybridization, and encodes for a protein having a different biological activity. For example, each nucleotide sequence is chemically, structurally

and functionally distinct from all other nucleotide sequences. A search for one nucleotide sequence would not be co-extensive with a search for another nucleotide sequence. Further, a finding that a nucleotide sequence, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that another nucleotide sequence is also novel and unobvious over the prior art. Also, each polypeptide sequence has a different melting temperature, a different specificity of hybridization, and encodes for a protein having a different biological activity. For example, each polypeptide sequence is chemically, structurally and functionally distinct from all other polypeptide sequences. A search for one polypeptide sequence would not be co-extensive with a search for another polypeptide sequence. Further, a finding that a polypeptide, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that another polypeptide sequence is also novel and unobvious over the prior art

Accordingly, each nucleotide sequence and each polypeptide sequence are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, should the applicant elect an invention drawn to amino acid sequences, the applicant must further elect a single amino acid sequence. Should the applicant elect and invention drawn to nucleic acid sequences, the applicant must further elect a single nucleotide sequence.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter as exemplified by their different classification, restriction for examination purposes as indicated is proper. Further, a search for Inventions I-VIII would not be co-extensive because a search indicating the method are novel or nonobvious would not extend to a holding that the products are novel or nonobvious; similarly, a search indicating that the method are known or would have been obvious would not extend to a holding that the products are known or would have been obvious.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner

Art Unit 1634
January 17, 2006

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER